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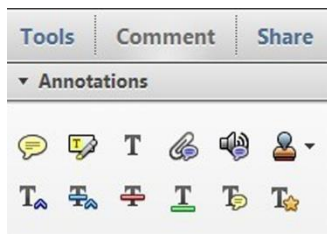


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Latest advancements in ureteral stent technology

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Abstract: Urological diseases such as tumours, kidney stones, or strictures in the ureter can lead to a number of health consequences, including life-threatening complications. Ureteral stents have been widely used as a valid solution to restore compromised urological function. Despite their clinical success, stents are subject to failure due to encrustation and biofilm formation, potentially leading to urinary tract infection. The current review focuses on recent advancements in ureteral stent technology, which have been reported in recent scientific journals or patents. Web of Science and Google Scholar have been used as a search engine to perform this review, using the keywords including but not limited to “Ureteral + Stent + Design”, “Ureteral + Stent + Material + Coating”, “Ureteric + Stent” and “Ureteral + Stent”. A significant proportion of technological developments has focused on innovating the stent design to overcome migration and urinary reflux, as well as investigating novel materials and coatings to prevent biofilm formation, such as poly(N,N-dimethylacrylamide) (PDMMA) and swellable polyethylene glycol diacrylate (PEGDA). Biodegradable ureteral stents (BUS) have also emerged as a new generation of endourological devices, overcoming the “forgotten stent syndrome” and reducing healthcare costs. Moreover, efforts have been made to develop pre-clinical test methods, both experimental and computational, which could be employed as a screening platform to inform the design of novel stent technologies.

Keywords: Ureteral stents; reflux; migration; biofilm; encrustation; computational fluid dynamics (CFD); design; material; test

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1 Introduction

2 The upper urinary tract can become obstructed because
3 of several physio-pathological conditions or diseases. The
4 aetiology of obstruction can be intraluminal (i.e., due to
5 renal or ureteral stones, ureteral strictures, or papillary
6 urothelial neoplasms) or extramural (i.e., due to advanced
7 urological or non-urological neoplasia). Ureteral blockages
8 increase the ureteric backpressure and—if left untreated—
9 can result in kidney failure. In 1960s, catheters made of
10 silicone rubber were introduced as the first generation of
11

12 ureteral stents and employed as a temporary measure to by-
13 pass ureteric blockages. Since then, the stent technology
14 has undergone many developments, encompassing the
15 constitutive material, surface coating, and design of the
16 stent. Currently, a typical stent architecture consists of a
17 22–24 cm long flexible tube made of polymeric or metallic
18 materials, with side-holes punched alongside its body. The
19 two extremities of the stent are J-shaped (also known as pig-
20 tail ends) and are designed to anchor the stent in the renal
21 pelvis and bladder, thus preventing it from migrating (1) (see
22 *Figure 1*).

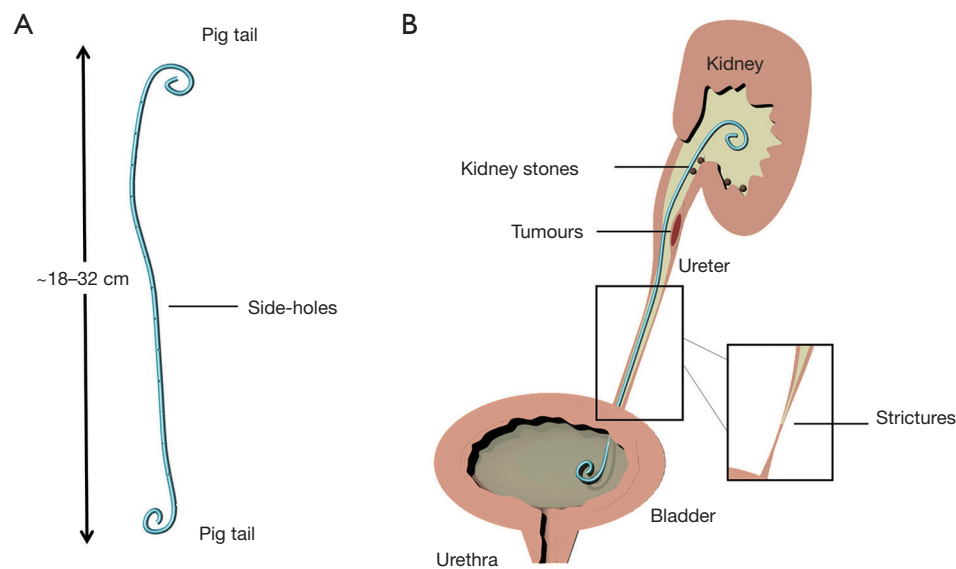


Figure 1 Ureteral stents are flexible tube-like devices with holes orthogonal to the length which allow for the passage of urine in case of ureteric obstruction. Pig tail ends in the stent help reducing migration of the stent and are located in the kidney and in the bladder. (A) A standard ureteral stent highlighting its key features (pig-tail ends and side-holes); (B) a cartoon of the urinary system illustrating common causes of ureteric obstruction and the placement of a double-J stent.

23 Over 1.5 million ureteral stents are used every year
 24 worldwide; however, it is estimated that >80% suffer
 25 from failure, which can cause severe pain and negatively
 26 impact on a patient's quality of life, may require surgical
 27 re-intervention, and ultimately increase the healthcare
 28 economic burden (2,3). Some of the underlying causes
 29 of failure are ureterovesical reflux, tissue irritation, and
 30 formation of infectious crystalline biofilms (4,5).

31 Over the last few years, a large body of research has
 32 focused on innovating the stent technology, predominately
 33 through the development of materials and architectural
 34 features that may prevent or delay stent-associated
 35 complications. These have been discussed in recent review
 36 articles (6,7). In the present review, we highlight the very
 37 recent advancements in stent technology.

38

39

40 **Advances in the constitutive materials or** 41 **surface coatings**

42

43 Several composite materials have been investigated for
 44 application in endourological devices (6,8); however, their
 45 usage has not led to a significant reduction in the incidence
 46 of stent encrustation or biofilm formation (9). The following
 47 section highlights recent advances in the constitutive
 materials of the stent, which are also summarised in *Table 1*.

48 Szell *et al.* (10) developed a coating agent to prevent
 49 biofilm formation on stents, in the form of a poly(N,N-
 50 dimethylacrylamide) (PDMAA) hydrogel with antifouling
 51 and protein-repellent properties. In their study, bacterial
 52 proliferation and adhesion were evaluated *in-vitro*. The
 53 hydrogel layer was deposited on both polyurethane
 54 (PU) and cyclin olefin polymer (COP) glass slides,
 55 which were incubated in sterile human urine for 48 h.
 56 Uropathogens were then added to the medium and, after
 57 further incubation (24 to 48 h), bacterial proliferation was
 58 quantified by CFU counting. PDMAA coating on both
 59 PU and COP surfaces significantly decreased (5-fold) the
 60 presence of bacteria adhered on the surface.

61 Some commercially available stents (e.g., Universa[®]
 62 Soft Ureteral Stent; COOK[®] Medical, Bloomington,
 63 IN, USA) are coated with hydrophilic hydrogels (usually
 64 PVA) that become lubricious and reduce surface friction
 65 upon deployment. Hydrogels can also be utilised as a
 66 substrate to achieve controlled release of biologically active
 67 compounds. For instance, Lim *et al.* (11) developed a drug-
 68 eluting ureteric stent, allowing for a constant drug release
 69 over time (up to 4–6 weeks, *in-vitro*) which improves drug
 70 absorption by the urothelium. The stent is spray-coated
 71 with a blend of a biodegradable polymer (70/30 poly-L-
 72 lactide-co-caprolactone, PLC) and an anti-proliferative

Table 1 Summary of key recent advances in ureteral stent design and materials, as well as stent characterisation methods

Improvement area	The change	Reference
Constitutive material	Coating agent for stent against biofilm formation (PDMMA)	Szell <i>et al.</i> (10)
	Drug-eluting and swellable stent (PEGDA)	Lim <i>et al.</i> (11)
	Biodegradable ureteral stent (BUS)	Barros <i>et al.</i> (12) & Soria <i>et al.</i> (13)
Stent design	Telescoping ureteral stent with anchoring system against migration	Pendleton <i>et al.</i> (14)
	Helical stent for controlling drainage	DeGraaf <i>et al.</i> (15)
	Non-coplanar pig-tails to avoid migration	Yachia <i>et al.</i> (16)
	J-tail in the kidney and anchoring structure in the bladder, to reduce reflux	McMahon <i>et al.</i> (17)
	Self-expandable mesh structure for anchoring in the bladder, and valve mechanism to prevent reflux	Shelton <i>et al.</i> (18)
Testing method	Mechanical testing: radial compression, self-expanding and self-stabilising, and friction	Yin <i>et al.</i> (19)
	Flow testing: in-house in-vitro model comprising serological pipettes shaped to accommodate stents	
	Constant and step compressive uniaxial loading to mimic extrinsic ureteric obstructions	Davis <i>et al.</i> (20)
	In-silico computational fluid dynamics (CFD) simulations replicating physiological properties, to minimise patient discomfort	Marzo <i>et al.</i> (21)
	Miniaturised experimental and CFD models replicating the obstructed urinary system, to design novel stent architectures against particle deposition	Mosayyebi <i>et al.</i> (23)

73 drug (mitomycin C, MMC). This layer is then coated with
 74 polyethylene glycol diacrylate (PEGDA) hydrogel. PEGDA
 75 is a swellable polymer, thus the size of this outer coating
 76 layer increases once the stent is deployed, reducing the
 77 gap between stent and urothelium (~1.5 mm). Moreover,
 78 the hydrogel layer prevents the drug from being rapidly
 79 washed away by the urine flow, and retains it in proximity
 80 to the stent. Such a stent could be potentially used for
 81 the treatment of diseases affecting the urothelium, such
 82 as tumours or strictures. A pilot *in-vivo* study in a porcine
 83 model also demonstrated that the stent inserts easily in the
 84 upper tract, does not damage the urothelium or compromise
 85 kidney function, and does not cause hydronephrosis or
 86 systemic toxicity.

87 One aspect of significant interest in the last year has been
 88 the evaluation of biodegradable ureteral stents (BUS) using
 89 porcine animal models *in-vivo*. Biodegradable stents present
 90 several benefits, such as decreased patient discomfort and
 91 anxiety, and reduction of healthcare costs (including those
 92 associated with the “forgotten stent syndrome”). They

are also particularly suitable for paediatric patients, to
 avoid anaesthesia during removal of the stent. BUS have
 been recently manufactured by Barros *et al.* (12), using an
 aqueous solution of gelatin-alginate-sodium salt and
 bismuth carbonate basic. Soria *et al.* (13) instead used a
 copolymer (Glycomer 631) and a polymer (polyglycolic
 acid). In both studies, BUS degradation took place in a
 controlled and predictable fashion, and no obstructive
 fragments appeared. Despite additional experiments are
 required to further validate this technology, it is evident
 that biodegradable stents represent an important avenue in
 future stent technology.

Advances in stent design

The development of novel stent designs has recently focused
 on stent architectures that could reduce tissue irritation
 and urinary reflux. The following section highlights recent
 advances in stent design (and their background claims),
 most of which have been patented. A summary of these

113 inventions is also provided in *Table 1*.

114 Pendleton *et al.* (14) introduced a telescoping ureteral
115 stent structure with the aim of improving stent patency;
116 this design has been translated into a commercial device by
117 COOK® Medical. It comprises a distal structure (located
118 towards the kidney) telescopically sliding into a proximal
119 structure (located towards the bladder). The invention
120 also involves a number of new anchoring mechanisms
121 that would act in two ways, (I) by stopping the stent
122 from migrating inside the ureter and (II) by preventing
123 the extended proximal end from returning back into the
124 ureter. Additionally, novel deployment methods have been
125 proposed for these stent models.

126 DeGraaf *et al.* (Boston Scientific Corporation, Grove,
127 MN, USA) (15) introduced an helical stent made of
128 polymeric materials, with the aim of controlling urine
129 drainage through the stent. The embodiments of this
130 invention consist of filaments with controlled extension
131 properties, which are coiled around the stent lumen,
132 together with a dissolvable coating. The degree of stent
133 extension is defined based on the material stiffness, filament
134 dimension, filament shape, and the method of extension.

135 Yachia *et al.* (Innoventions Ltd., Akiva, Israel) (16)
136 invented a stent design that aims to reduce patient's
137 discomfort and flank pain. It relies on having both pig-
138 tail ends non-coplanar with respect to the bladder trigone.
139 The proximal end consists of a sleeve made of a softer
140 material, which allows controlling the expansion of the pig
141 tail depending on the level of urine force compared to the
142 sleeve radial tensile force. Additionally, they introduced
143 different shapes of the proximal region with the aim of
144 preventing urine reflux from the bladder towards the
145 kidney, due to increased bladder pressure. Another design
146 element is a pre-shaped wire (made of polymer or metal)
147 that is inserted through a small lumen parallel to the main
148 stent lumen, with the purpose of retaining the curly shape
149 of the stent.

150 McMahon *et al.* (Baylor University, Texas, USA) (17)
151 introduced a stent design with potential for reducing
152 ureterovesical reflux. It includes a distal J-end (kidney) and
153 a novel anchoring structure at the proximal end (bladder).
154 The lumen is designed to have a narrower cross-section
155 in the bladder, in order to reduce bladder irritation. This
156 segment of the stent could be expanded or folded depending
157 on the level of anchoring required. Moreover, a flapper
158 valve was designed at the bladder end, which closes when
159 the bladder pressure increases in order to prevent reflux.

160 Shelton *et al.* (Gyrus ACMI®, Massachusetts, USA) (18)

introduced a series of ureteral stent designs, with the aim 161
of reducing urothelial tissue irritation, particularly at the 162
bladder trigone and the uretero-vesical junction (UVJ). 163
This design concept relies on projections (with different 164
shape, length, size, and orientation), a self-expandable 165
mesh structure anchoring in proximity to the UVJ, and 166
coiled tails which may have a different internal diameter 167
compared to the ureteric section of the stent. The invention 168
also includes the integration with a valving mechanism to 169
prevent reflux. 170

171 Pre-clinical testing of stent function 172

173 Yin *et al.* (19) introduced a novel stent manufacturing 174
technology based on freeze-casting, in order to generate 175
porous stents with improved urine drainage. In their study, 176
stents manufactured with this technique were compared to 177
standard 8 Fr double-J stent (Universa® Soft Ureteral Stent 178
with Hydrophilic Coating, Cook® Medical, Bloomington, 179
IN, USA). To understand the surface structure, both types 180
of stent were imaged by scanning electron microscopy 181
(SEM) and confocal microscopy, to characterise transverse 182
and longitudinal sections, and both inner and outer surfaces 183
of the stent. Mechanical testing was performed, including 184
radial compression, self-expanding and self-stabilising 185
testing, and friction testing (to determine the friction force 186
due to a known displacement rate of 0.01 mm/s). The flow 187
performance of the stent was investigated using an in-vitro 188
model developed in house, comprising serological pipettes 189
that were shaped to accommodate a stent. Results from 190
these tests showed that the porous stent had improved 191
drainage compared to the standard one. 192

193 Davis *et al.* (20) developed a method to investigate the 194
ability of stents to resist extrinsic ureteric obstructions. It 195
relies on the application of a constant or step compressive 196
uniaxial loading in a direction orthogonal to the stent axis, 197
at three different locations (proximal, central, and distal). 198
Two types of load were investigated which were applied 199
through (I) a 625 mm² square surface simulating a large 200
extrinsic obstruction, and (II) a metal rod (1 mm radius) to 201
simulate a confined obstruction.

202 Marzo *et al.* (21) introduced an efficient urinary 203
drainage test system, specifically designed for urethral 204
catheters. They employed theoretical analytical method, 205
computational fluid dynamics (CFD) simulations and a 206
standard experimental design to investigate the effect of 207
catheter diameter on urinary drainage, with the ultimate 208
goal of identifying a catheter design that could reduce

209 patient discomfort. Their theoretical model was designed to
 210 replicate the physiological properties of the urinary system,
 211 specifically bladder and urethral region (geometry and flow
 212 dynamics of the urine flow through a bent tube). Results
 213 show that reducing the catheter inner diameter by half of its
 214 original size would significantly improve clinical tolerability
 215 while maintaining an acceptable flow rate. Moreover, the
 216 CFD simulation package allowed investigating the effect of
 217 catheter design changes on the spatial distribution of wall
 218 shear stress (WSS) and urine velocity.

219 The utility of CFD modelling as a tool to innovate stent
 220 design is also evident in the work by Mosayyebi *et al.* (22).
 221 In their earlier study (23), they developed a microfluidic
 222 platform (known as ‘stent-on-chip’) to investigate the
 223 mechanism of particle accumulation in ureteric stents.
 224 Using this model, they demonstrated an inverse correlation
 225 between the magnitude of shear stress acting on the
 226 stent surface (computed from CFD simulations) and the
 227 accumulation of encrusting particles. Moreover, they
 228 identified regions of the stent that are more likely to suffer
 229 from encrustation, such as inactive side-holes and other
 230 stagnant regions in the vicinity of a ureteric obstruction.
 231 Results qualitatively agreed with observations on stents
 232 retrieved from patients. Building upon this study, the
 233 same group investigated changes to the stent geometry,
 234 by varying the stent wall thickness and the shape of side-
 235 holes. They concluded that a thinner stent with streamlined
 236 side holes offers a 90% reduction in particle deposition
 237 compared to a standard stent design.

238
 239

Conclusions

240 The present manuscript reviews recent developments in
 241 stent technology, with a focus on stent material, design,
 242 and characterisation methods. The most notable advances
 243 in stent materials include antibacterial and drug-eluting
 244 coatings, and biodegradable stents. Innovations in the stent
 245 design focused on reducing ureterovesical reflux, stent
 246 migration, and tissue irritation.

248 Despite significant efforts have been devoted to the
 249 improvement of current stent technologies, an ideal stent
 250 that does not suffer from failure and complications does
 251 not yet exist. However, we anticipate that this could be
 252 achieved through simultaneous developments of multiple
 253 technological features and properties of a stent, and by
 254 establishing appropriate computational and experimental
 255 design optimisation and verification procedures.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest
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Ethical Statement: The authors are accountable for all
 aspects of the work in ensuring that questions related
 to the accuracy or integrity of any part of the work are
 appropriately investigated and resolved.

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